UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: Canadian Import Antitrust Litigation

Civ. No. 04-2724 (JNE/JGL)
ORDER

Plaintiffs claim that Defendants violated federal antitrust law, various states' restraint-of-trade statutes, and common law by engaging in a course of conduct designed to suppress the importation of prescription drugs purchased from Canadian pharmacies for personal use in the United States. This case is before the Court on two separate Report and Recommendations issued by the Honorable Jonathan Lebedoff, Chief United States Magistrate Judge, on February 28, 2005 (February Report), and March 18, 2005 (March Report), respectively. Objections to both Report and Recommendations and responses thereto have been filed.

In the February Report, the magistrate judge recommended that the Court dismiss Plaintiffs' federal antitrust claim (Count I of Pls. Consol. Compl.) because Plaintiffs lack standing to challenge Defendants' allegedly anti-competitive conduct under the Sherman Act. In addition, the magistrate judge concluded that federal law does not preempt Plaintiffs' state-law claims (Count II) and that the Court has not been provided a legal framework to universally strike Plaintiffs' equitable claims (Count III), which are traditionally reviewed under state law. Accordingly, the magistrate judge recommended denying Defendants' motion to dismiss Plaintiffs' claims under state and common law.

In the March Report, the magistrate judge considered Defendant Novartis AG's and Defendant AstraZeneca PLC's motions to dismiss for lack of jurisdiction and improper venue. The magistrate judge recommended that these motions be granted in part and denied in part and

that Counts II and III of Plaintiffs' Consolidated Complaint, as alleged against Novartis and AstraZeneca, be dismissed.

Based on a de novo review of the record, the Court adopts the magistrate judge's recommendation that Plaintiffs' federal antitrust claim be dismissed and declines to adopt the magistrate judge's remaining recommendations for the reasons stated below.

I. February Report

With respect to the magistrate judge's recommendation that Plaintiffs' federal claim be dismissed, the magistrate judge concluded that prescription drugs imported from Canada for personal use are misbranded under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, the magistrate judge found that the transport of drugs for personal use into the United States constitutes an "introduction into interstate commerce" under the FFDCA. Further, the magistrate judge concluded that Plaintiffs lack standing to challenge Defendants' allegedly anti-competitive behavior because the importation of these drugs is unlawful and, therefore, not the type of activity which federal antitrust laws were designed to protect.

Plaintiffs object only to the magistrate judge's conclusion that misbranding occurs when prescription drugs purchased by American consumers in Canada enter the United States. Based on a de novo review of the record, and for the reasons stated in the February Report, the Court adopts this conclusion and finds that prescription drugs purchased in Canada by American consumers for personal use in the United States are misbranded if introduced into United States' commerce.

In particular, the Court reiterates that such drugs are misbranded because their labels do not bear the "Rx only" symbol prior to dispensing. *See* 21 U.S.C. § 353(b)(4)(A) (2000). Plaintiffs do not contend that the imported drugs bear the "Rx only" symbol. Instead, they

concede that these drugs bear a "Pr" symbol, which is required under Canadian law. Plaintiffs argue, however, that the lack of the "Rx only" symbol is not fatal to their federal claim because (1) section 353(b)(4) does not apply to drugs dispensed in Canada; (2) section 353(b)(4) does not require the "Rx only" symbol; and (3) Canada's "Pr" symbol is interchangeable with the United States' "Rx only" symbol with respect to the drugs at issue in this case. These arguments fail. First, the statute clearly requires that the "Rx only" symbol appear on drugs prior to dispensing. Section 353(b)(4) reads: "A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only.'" Contrary to Plaintiffs' contention, there is no exception for drugs dispensed outside of the United States.[1] Second, there is no serious dispute that the drugs bearing the "Pr" symbol fail to satisfy the statute's unequivocal requirement that the relevant drugs bear "at a minimum, the symbol 'Rx only.'" No reasonable reading allows for the use of the "Pr" symbol instead of the "Rx only" symbol. Third, Plaintiffs ask the Court to make the "practical finding" that Canada's "Pr" symbol satisfies the requirements of section 353(b)(4), "at least with respect to drugs dispensed in Canada where the 'Pr' symbol has the same function as the 'Rx' symbol." (Pls.' Objections at 10.) The Court declines to make such a finding. Section 353(b)(4) does not allow for the substitution of another country's "equivalent" symbol for the United States' "Rx only" symbol. The Court notes that the courts are not the proper forum to determine whether Canada's or another country's prescription drug labels or symbols function in the same manner or offer the same protections as the United States' "Rx only" symbol.

[1] That there is no such exception makes sense in light of the FFDCA's prohibition of the "introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a) (2000).

The magistrate judge also correctly concluded that Canadian drugs fail to satisfy various other FFDCA labeling requirements. February Report at 12-13. For example, the Canadian drugs are misbranded because they use a Canadian Identification Number instead of a United States National Drug Code. *See* 21 C.F.R. §§ 201.2, 207.35(b)(2). Plaintiffs contend, without citation to authority, that section 353(b)(2) exempts drugs dispensed by a Canadian pharmacist from these requirements. The Court disagrees. Section 353(b)(2) provides that any drug dispensed by filling a prescription of a practitioner licensed by law to administer such drug shall be exempt from certain requirements of section 352 if various conditions are met.[2] Plaintiffs' proposed reading of this "pharmacist exemption" would allow misbranded drugs to be legally introduced into the United States simply because the drugs were dispensed by a pharmacist outside of the United States. This reading, however, is at odds with the United States' comprehensive scheme under which drugs are regulated. The Court, therefore, rejects this interpretation and finds that a drug that is introduced into the United States is not exempt from the FFDCA's labeling requirements simply because it is dispensed by a pharmacist outside of the United States. The Court also notes that this exemption does not become effective until the moment the relevant drugs are dispensed on prescription. *See United States v. Article of Drug BIFLAV-C-2*, 292 F. Supp. 346, 348 (C.D. Cal. 1968). Prior to the time of dispensing, the "pharmacist exemption" is not effective and "does not exempt the drugs from any of the labeling requirements." *Id*. Therefore, even if the exemption applied to drugs dispensed by Canadian pharmacists, it would not exempt the Canadian drugs from the FFDCA's labeling requirements prior to being dispensed.

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[2] Section 352 provides that drugs are misbranded if they lack certain required labeling information. 21 U.S.C. § 352 (2000). The "pharmacist exemption" of section 353(b)(2) permits a pharmacist to dispense drugs into a smaller container without including all of the labeling requirements of section 352.

Finally, the Court notes that other legislation underscores the illegality of importing drugs from Canada. For example, both the Medicine Equity and Drug Safety Act of 2000, which added section 804 (21 U.S.C. § 384) to the FFDCA, and the Medicare Modernization Act of 2003, which later modified section 804, would authorize limited importation of prescription drugs if certain conditions are met, but only if the Secretary of Health and Human Services "certifies to the Congress that the implementation of this section will pose no additional risk to the public's health and safety; and result in a significant reduction in the cost of covered products to the American consumer." 21 U.S.C. § 384(*l*). There is no evidence, and Plaintiffs do not argue, that such certification has been made.

For these reasons, the Court agrees with the magistrate judge's conclusion that prescription drugs imported from Canada for personal use in the United States are misbranded. The Court also agrees with the magistrate judge's conclusions that the transport of drugs for personal use into the United States constitutes an "introduction into interstate commerce" under the FFDCA, that no fact questions regarding interstate commerce exist, and that Plaintiffs lack standing to assert a cause of action under the Sherman Act. Accordingly, the Court adopts the magistrate judge's recommendation to dismiss Count I of Plaintiffs' Consolidated Complaint.

In their Consolidated Complaint, Plaintiffs also allege that Defendants' actions violate the laws of more than twenty states. In the February Report, the magistrate judge recommended denying Defendants' motion to dismiss these claims. The Court notes, however, that the sole basis for its jurisdiction over Plaintiffs' remaining claims is 28 U.S.C. § 1367(a) (2000). Section 1367(a) permits a district court to exercise supplemental jurisdiction over claims that are part of the same case or controversy as the claims that fall within the district court's original jurisdiction. A district court may, in its discretion, decline to exercise supplemental jurisdiction

when "all claims over which it has original jurisdiction" have been dismissed. 28 U.S.C. § 1367(c)(3); *see Franklin v. Zain*, 152 F.3d 783, 786 (8th Cir. 1998); *Save Our Health Org. v. Recomp of Minn., Inc.*, 829 F. Supp. 288, 293 (D. Minn. 1993), *aff'd*, 37 F.3d 1334 (8th Cir. 1994). In this case, the Court has dismissed Plaintiffs' federal antitrust claim, the only claim within the Court's original jurisdiction. The Court declines to exercise its supplemental jurisdiction over Plaintiffs' remaining state-law and common-law claims and dismisses them without prejudice. The Court, therefore, denies Defendants' motion to dismiss Counts II and III of the Consolidated Complaint as moot.

II. March Report

In the March Report, the magistrate judge considered both Novartis' and AstraZeneca's motions to dismiss for lack of jurisdiction and improper venue. Because the Court has dismissed Plaintiffs' federal antitrust claim and declines to exercise supplemental jurisdiction over the remaining state-law and common-law claims, the issues discussed in the March Report are moot.

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Defendants' Motion to Dismiss the Consolidated Complaint [Docket No. 98] is GRANTED IN PART and DENIED IN PART AS MOOT.

2. Count I of Plaintiffs' Consolidated Complaint is DISMISSED WITH PREJUDICE.

3. Counts II and III of Plaintiffs' Consolidated Complaint are DISMISSED WITHOUT PREJUDICE.

4. Defendant Novartis AG's Motion to Dismiss for Lack of Jurisdiction and Improper Venue [Docket No. 92] is DENIED AS MOOT.

5. Defendant AstraZeneca PLC's Motion to Dismiss for Lack of Jurisdiction and Improper Venue [Docket No. 99] is DENIED AS MOOT.

6. Plaintiffs' Motion for Leave to File Supplemental Authority [Docket No. 206] is GRANTED.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: August 26, 2005

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge